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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,374	02/16/2001	Anthony M. Looper	VM 6010.2	5023

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

HCT

Office Action Summary

Application No.

09/785,374

Applicant(s)

LOOPER ET AL.

Examiner

Mital B. Patel

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-89 is/are pending in the application.
- 4a) Of the above claim(s) 22-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13,15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 10/2/02 have been fully considered but they are not persuasive.
2. In response to applicant's argument (with respect to claim 1 and its dependents) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a tissue engaging means and a handle assembly and an actuating means) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please note that the Applicant only positively recites a shaft member not the combination of the shaft member and the tissue engaging means and a handle assembly and an actuating means. Therefore, Stevens does teach all of the claimed limitations.
3. In response to Applicant's arguments with respect to U.S. Patent No. 5643303 to Donahue, the Examiner considers elements 50 and 54 in Figure 8 to be first and second opposed jaws.

Information Disclosure Statement

4. It should also be noted that the IDS filed by the Applicant includes 11 sheets, however, page 3 of 11 is missing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-12, 13, and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. As set forth by claims 1 and 13, it is unclear as to what exactly the Applicant means by the term "fatigue resistant". Applicant has not provided sufficient language and structure in the claims to define "fatigue resistant".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al (US 5916193).
10. **As to claim 1**, Stevens teaches a malleable shaft member for a surgical device having a tissue engaging means and a handle assembly, and an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means, the shaft member **320** comprising a first tube **322** made of a malleable

Art Unit: 3761

material and having a proximal end **326**, a distal end **324** and a longitudinal axis, the proximal end of the first tube adapted to be coupled to the handle assembly, the distal end of the first tube adapted to be coupled to the tissue engaging means, the actuating means adapted to extend axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (See Col. 27, lines 45-67 and Col. 28, lines 1-21). Stevens is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Stevens and therefore, the shaft member of Stevens is fully capable of bending in the range disclosed.

11. **As to claims 3-4**, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Stevens, and therefore, the shaft member of Stevens is fully capable of bending in the range disclosed.

12. **As to claims 5 and 7**, Stevens teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

13. **As to claim 6**, Stevens teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass.

14. **As to claim 8**, Stevens teaches a shaft member wherein the proximal end of the first tube is adapted to be removably coupled to the handle assembly.

15. **As to claim 9**, Stevens teaches a shaft member wherein the distal end of the first tube is adapted to be removably coupled to the tissue engaging means.

16. **As to claim 10**, Stevens teaches a shaft member further comprising a second tube **352**, the first tube coaxially aligned and disposed within the second tube (See Col. 26, lines 27-29).

17. **As to claim 11**, Stevens teaches a shaft member wherein the second tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

18. **As to claim 12**, Stevens teaches a shaft member wherein the first and second tubes are formed from co-extrusion (See Fig. 29B).

19. Claims 13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donahue (US 5643303).

20. **As to claim 13**, Donahue teaches a surgical device (Fig. 8) comprising a tissue engaging means including first and second opposed jaws **50,54** for grasping, securing, and occluding body tissue and conduits; a handle assembly **52**, and an actuating means **46** connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means, a malleable shaft member **42** comprising a first tube made of a

Art Unit: 3761

malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the first tube coupled to the handle assembly, the distal end of the first tube coupled to the tissue engaging means, the actuating means extending axially through the first tube, the first tube configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending moment applied to the first tube (See Col. 5, lines 4-26). Donahue is silent to the specific range of bending moment. However, Applicant has not provided sufficient structure to result in structural differences between the claimed invention and the shaft of Donahue and therefore, the shaft member of Donahue is fully capable of bending in the range disclosed.

21. **As to claim 15**, the Applicant has not provided sufficient language and structure to result in structural differences between the claimed invention and the shaft of Donahue, and therefore, the shaft member of Donahue is fully capable of bending in the range disclosed.

22. **As to claim 16**, Donahue teaches essentially all of the limitations except for the specifics of the wall thickness. However, it would be obvious to one of ordinary skill in the art to arrive at the particular dimensions depending on what specific medical procedure or surgical procedure the shaft member was required from since different sized tubes are used for different parts of the body when performing a surgical or medical procedure.

23. **As to claim 17**, Donahue teaches a shaft member wherein the first tube is made of material selected from the group consisting of stainless steel, copper, aluminum, and brass.

Art Unit: 3761

24. **As to claims 18 and 19**, Donahue teaches essentially all of the limitations except for wherein the shaft member is removably coupled to the handle assembly and the tissue engaging means. However, it would have been obvious to one of ordinary skill in the art to make the parts removably couplable so that if a part needed to be replaced it would be easier to replace the part than the entire device. Furthermore, it would be obvious to one of ordinary skill in the art to make the parts removably couplable so that the parts can be easily cleaned.

25. **As to claim 20**, Donahue teaches a surgical device further comprising an outer tube **44**, the first tube coaxially aligned and disposed within the second tube.

26. **As to claim 21**, Donahue teaches a surgical device wherein the outer tube is made of material selected from the group consisting of aluminum, brass, copper and plastic.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3761

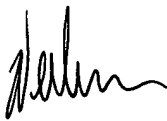
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
January 2, 2003


WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700